

**R E M A R K S**

Reconsideration of this application, as amended, is respectfully requested.

**THE CLAIMS**

The claims have been amended to more positively recite the patentably distinguishing structural features of the invention, as well as to make some minor grammatical improvements and to correct some minor antecedent basis problems.

In particular, it is noted that claims 1, 2 and 12 have been amended to avoid positively reciting parts of the human body, and to instead recite the structural features of the invention as being "adapted to" engage parts of the human body. Accordingly, it is respectfully submitted that the present invention as recited in the amended claims is now clearly directed to statutory subject matter, and it is respectfully requested that the rejection under 35 USC 101 be withdrawn.

In addition, claim 1 has been amended to more clearly recite the positioning of the needle (44) within the body cavity and relative to the holding device (11), as supported by the disclosure in the specification at, for example, page 9, paragraphs 53 and 54 as well as by the disclosure in Fig. 15.

Still further, it is noted that the grammatical informalities pointed out by the Examiner in item 3 of the Office

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Action have been corrected, thereby overcoming the Examiner's objections to claims 2, 8 and 12.

And with respect to withdrawn claim 7, it is noted that this claim depends from claim 6 and generic claim 1. Accordingly, it is respectfully requested that claim 7 be rejoined and considered upon a determination of the allowability of claims 1 and 6 from which claim 7 depends.

No new matter has been added to the claims, and it is respectfully requested that the amendments to the claims be approved and entered.

#### THE PRIOR ART REJECTION

Claims 1, 3, 4 and 8-12 were rejected under 35 USC 102 as being anticipated by Matsui et al (USP 6,352,503), claim 2 was rejected under 35 USC 103 as being obvious in view of the combination of Matsui et al and Mangum (USP 5,397,326), and claims 6 and 20 were rejected under 35 USC 103 as being obvious in view of the combination of Matsui et al and Mills et al (USP 5,037,021). These rejections, however, are respectfully traversed with respect to the claims as amended hereinabove.

As recognized by the Examiner, Matsui et al discloses in Figs. 44-47 thereof an apparatus for forming an artificial valve between the esophagus and the stomach. More specifically, according to the description at column 17, lines 23-45 of Matsui

et al, a grasping forceps 186 and a clipping device 187 are inserted into the stomach through a channel 121 of an endoscope. And as shown in Fig. 45 of Matsui et al, the cardia part of the stomach is pulled down by the grasping forceps 186, and the clipping device 187 is then attached to form an artificial valve. In Matsui et al, the clipping device 187 is left inside the stomach to keep the shape of the artificial valve.

With the structure of Matsui et al, however, when food passes through the cardia part into the stomach, the clipping device sometimes interferes with the food. Therefore, there is a possibility that the clipping device will detach from the clipped part of the stomach wall. In addition, a similar situation will possibly occur when an endoscope is inserted into the stomach through the cardia part. And if the clipping device is detached the artificial valve is lost.

According to the structure of the present invention as recited in an amended claim 1, by contrast, an artificial valve is formed by using a needle and a suture. Therefore, after the valve is formed, there is no clipping device attached to the artificial valve.

More specifically, the structure of the present invention as recited in amended claim 1 comprises: a first endoscope adapted to be orally inserted into a body cavity; a holding device extending out of a distal end of the first endoscope and adapted

to hold a point of a digestive wall of the body cavity where an artificial valve is to be formed; a first needle that is moveable in a longitudinal direction of the first endoscope and that includes a sharp end adapted to penetrate the digestive wall, wherein the first needle is adapted to be positioned at an oral side of the holding device before piercing the digestive wall; a suture adapted to pass through the digestive wall following the first needle; and a suture retaining device having a grasping section adapted to grasp the suture after the suture has passed through the digestive wall.

With this structure an artificial valve can be formed using a needle and a suture by pulling down a part of the stomach wall utilizing the holding device as shown in Figs. 12-14 of the present application, and then piercing the pulled down wall with the needle for passing the suture through the base portion of the pulled-down wall. Therefore, the easiest way to operate is to position the needle at an upper side of the holding device, that is, on an oral side of the pulled down wall of the stomach before the needle pierces the wall, as shown in Fig. 15 - and as recited in amended claim 1. As can easily be understood from the example shown in Fig. 15, it is hard to bring the needle 44 to the lower side of the holding device 11 (i.e., the anal side of the pulled-down wall) around the pulled-down wall because the wall itself

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acts as an obstruction preventing the needle from going to the lower portion.

It is noted that Fig. 11 of Matsui et al also discloses an apparatus using a needle and a suture. It is respectfully submitted, however, that as described at column 9, lines 18-38 of Matsui et al, this apparatus is used for sewing a cut-opened portion of living tissue - and is not used for forming an artificial valve.

It is respectfully submitted, moreover, that Mangum and Mills et al et al also fail to disclose, teach or suggest the above described features and advantageous effects of the needle, suture and holding device structure of the present invention as recited in amended claim 1.

Accordingly, it is respectfully submitted that amended claim 1, as well as claims 2-4, 6-12 and 20 depending therefrom, all patentably distinguish over the cited references, taken singly or in any combination, under 35 USC 102 as well as under 35 USC 103.

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In view of the foregoing, entry of this Amendment, allowance of the claims and the passing of this application to issue are respectfully solicited..

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If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,



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